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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,208	01/12/2004	B. Robert Mozayeni	05162.0004.CPUS13	8736

22930 7590 07/03/2007

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EXAMINER	
JAWORSKI, FRANCIS J	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
07/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary	Application No.	Applicant(s)	
	10/755,208	MOZAYENI ET AL.	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11-1-04 IDS*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 – 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No prior step of intracranial bloodflow data obtainance is recited in the base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 2, 4 – 11, 13 - 15 (where 'intracranial' in claim 8 is accorded no weight, see above), 13 - 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Haude et al (Circulation 2001:103:1212 (2001), of record herewith).

Haude et al is directed to a method of assisting a stenting procedure comprising obtaining a first set of maximum blood velocity data and generating at least two blood flow factors from this set, where (referring to Methods, Coronary BF Velocity Measurements within the article) the following plurality of factor sets are generated:

Individual peak or maximum BF sample and averaged peak BF, and/or

Baseline sample/average of samples and hyperemic value, and/or absolute coronary flow velocity reserve (CVR) therefrom and or CVRrel as CVR (absolute) in the vessel being stented reverenced to an unobstructed control vessel in the same patient,

any or all of these representing functional correlations between the factor types, and assessing blood flow prior to stenting as well as flow improvement post stenting in relation to major adverse coronary event risk at the intracoronary site whose flow is being assessed. Peak velocity occurs in the systolic interval as shown Fig. 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haude et al as argued against claim 2 above, further in view of St. Germain et al (US5534007), since the latter evidences per geometry of stent 35 in Figs. 1 – 3 that staged deployment would have been a conventional delivery routine for a catheter-delivered stent as per the former.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haude et al as applied to claim 8 above, and further in view of Lee et al (US6697667) since col. 1 lines 54 – 58 and Fig. 4 elements 30,34,66,68 and the LDV analyzer of the latter evidence that it would have been conventional for example to perform Doppler flow studies using laser technology alternative to ultrasound during stent deployment e.g. in the coronaries.

Claims 16 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haude et al as applied to claim 1 above, and further in view of Dinh et al (US5,510,077). Whereas the former is not concerned with stent design, the latter col. 1 evidences that MACE type sequellae such as in the former would feedback into the re-working of the stent by incorporating design improvements to reduce the rate of adverse outcomes, whereupon the bloodflow-measurement-based assessment and risk evaluation process does in fact feed back into stent design improvement. In the case of Dinh et al a fibrin – thrombinogen biochemical film or coating may be applied (col. 5 lines 42 – 48). The ratio formations and risk threshold calculations in Haude et al per se constitute a schema which uses the bloodflow measurement values.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

6-20-07

Francis J. Jaworski
Primary Examiner